JUN 13 2012

510(k) Summary

Date:	2 February 2012
Sponsor:	Nexxt Spine LLC 10100 Lantern Road, Ste 200 Fishers, IN 46037 Phone: 317.436.7801 Facsimile: 317.245.2518
Contact Person:	Andy Elsbury, President
Trade Names:	HONOUR™ Spacer System
Device Classification	Class II
Classification Name:	Spinal vertebral body replacement device; Intervertebral fusion device with bone graft, lumbar/cervical
Regulation:	888.3060 and 888.3080
Device Product Codes:	MQP and MAX/ODP
Device Description:	The HONOUR™ Spacer System is a collection of radiolucent cage devices. The basic shape of these implants is a structural column. The superior and inferior surfaces are open with serrations to facilitate implant stability. The implants are available in an assortment of height, length, width and anteroposterior angulation combinations to accommodate a variety of anatomic requirements.
Intended Use:	When used as a cervical intervertebral fusion device, the HONOUR™ devices are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine (e.g., the Blade® Anterior Cervical Plate System). When used as a lumbar intervertebral fusion device, the HONOUR™ devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous graft and with supplemental fixation systems cleared for use in the lumbar spine (e.g., the Inertia® Pedicle Screw System). When used as a vertebral body replacement device, the HONOUR™ devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the

spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation systems cleared for use in the thoracolumbar spine (e.g., the Inertia® Pedicle Screw System).

Materials: HONOUR™ Spacers are manufactured from polyetheretherketone (Solvay Zeniva® ZA-500 PEEK) per ASTM F2026. Integral marker pins are manufactured from tantalum according to ASTM F560.

Predicate Devices: Lumbar I/F Cage® (P960025)

AVS PEEK Spacers (K042571, K050624, K061836, K062132, K073470, K082014, K083661 and K093704)

Stealth™ (K091531)

Construx™ (K051246)

Pillar™ PL/TL (K081177)

Technological Characteristics: The HONOUR™ Spacer System devices possess the same technological characteristics as the predicate devices. These include:

- intended use (as described above),
- basic design (hollow structural frame),
- material (polymer or CFRP), and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate systems).

Therefore the fundamental scientific technology of the HONOUR™ Spacer System devices is the same as previously cleared devices.

Performance Data: Mechanical testing of the worst case HONOUR spacer was performed according to ASTM F2077 and included static and dynamic compression and static and dynamic torsion. In addition, the subsidence properties were evaluated according to ASTM F2267.

The mechanical test results demonstrate that the HONOUR™ Spacer System devices perform as well as or better than the predicate devices. Hence these devices are as safe and as effective as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 13 2012

Nexxt Spine, LLC
% Backroads Consulting, Inc.
Karen Warden, Ph.D.
P.O. Box 566
Chesterland, Ohio 44026

Re: K120345
Trade/Device Name: Honour Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP, MAX, MQP
Dated: May 16, 2012
Received: May 18, 2012

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120345

Device Name: **HONOUR™ Spacer System**

Indications for Use:

When used as a cervical intervertebral fusion device, the HONOUR™ devices are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine (e.g., the Blade® Anterior Cervical Plate System).

When used as a lumbar intervertebral fusion device, the HONOUR™ devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the lumbar spine (e.g., the Inertia® Pedicle Screw System).

When used as a vertebral body replacement device, the HONOUR™ devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation systems cleared for use in the thoracolumbar spine (e.g., the Inertia® Pedicle Screw System).

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120345